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Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0529]

Pfizer, Inc.; Withdrawal of Approval of a New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for REZULIN (troglitazone) Tablets held by Pfizer, Inc., 235 East 42d Street, New York, NY 10017. Pfizer has voluntarily withdrawn this NDA because the product is no longer marketed, thereby waiving its opportunity for a hearing.

DATES: Effective [insert date of publication in the FEDERAL REGISTER.]

FOR FURTHER INFORMATION CONTACT:

Florine P. Purdie,

Center for Drug Evaluation and Research (HFD-7),

Food and Drug Administration,

5600 Fishers Lane,

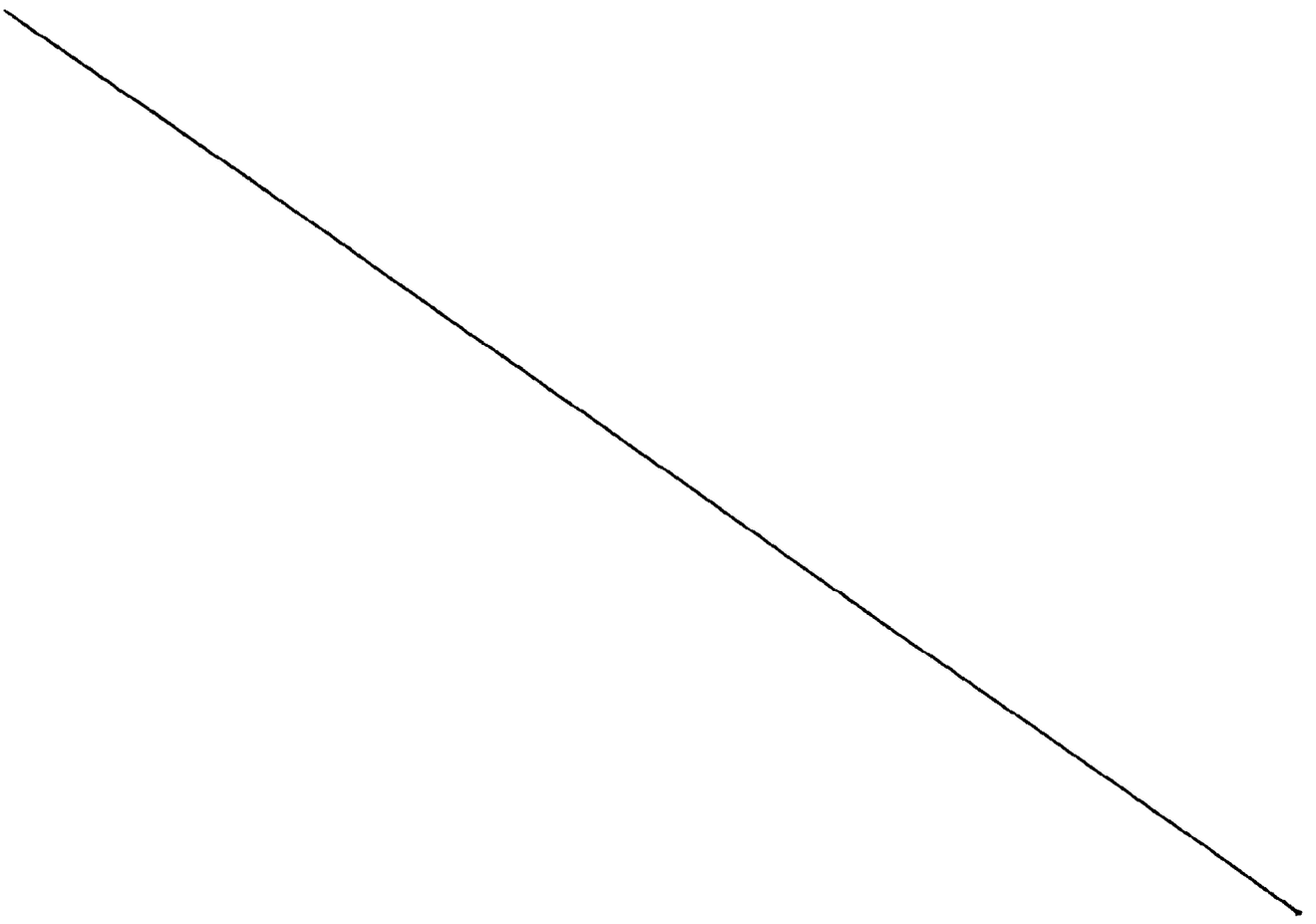
Rockville, MD 20857,

301-594-2041.

SUPPLEMENTARY INFORMATION: In a letter dated May 1, 2002, Pfizer, Inc., requested that FDA withdraw under § 314.150(d) (21 CFR 314.150(d)), NDA 20-720 for REZULIN (troglitazone) Tablets,

stating that The Warner-Lambert Co., which Pfizer acquired in June 2000, discontinued marketing the product in March 2000. REZULIN (troglitazone) Tablets, a treatment for type 2 diabetes, was voluntarily withdrawn after review of safety data showed that the drug is more toxic to the liver than two other more recently approved drugs that offer a similar benefit. Pfizer waived its opportunity for a hearing, provided under § 314.150(a) and (b).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.105(a)), approval of the NDA 20-720, and all amendments and supplements thereto, is withdrawn.



Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the act (21 U.S.C. 355(a) and 331(d)).

Dated: 12/16/02
December 16, 2002.

Janet Woodcock,
Director,
Center for Drug Evaluation and Research.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
Dawn P. Hawkins